



# Healthy Aging in Neighborhoods of Diversity across the Life Span

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## The Healthy Journey

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### HANDLS WAVE 3 PROTOCOL OVERVIEW

As you know, HANDLS is studying aging and health in different kinds of people over a long period of time. HANDLS is new type of study because one of our goals is to partner with each of you in carefully checking your health. To do this, we plan to repeat your health assessments every 3 or 4 years. These visits will help us understand health changes and differences better. Perhaps more importantly, these visits will also give you important information about your health. We hope that giving you these regular facts about your health will help you avoid certain diseases or make them less severe if you get them.

The coming exams will have some of the same tests you had before. This is very important because it will help us to compare how your health is now to your health when your first joined the study. There are also new exams that give you information about how well your heart, brain and kidneys are working. Dr. Ejiogu and our nurses, Ms. Mary Sam and Ms. Kitty, are looking forward to catching up with you about how your health has been since the last time we saw you. As always, they are happy to answer any questions you have about your health or about new conditions

that might have come up since we saw you last. Ms. Mary, Ms. Clare, and memory testers, Angela, Liz, and Joyce are all excited about revisiting all the neighborhoods and seeing everyone again, too. The best way to your health is to get regular thorough exams when you are not acutely sick. HANDLS is a good way to stay in touch with your body and stay healthy.

For this wave of the study, we will not visit you in your home. We will invite your to return to the medical research vehicles for an exam that takes about 4½ hours. We will then call you on the telephone at home so that you can tell us for a second time about your eating patterns. Your eating patterns and habits are an important key to healthy living so we think talking about it with you 2 times, once on the vehicles and once over the telephone is important. We will still provide transportation to and from the vehicles and breakfast and lunch from our new caterer, *A Love Affair Catering*. Based on your comments, we will strive to provide the healthiest and best tasting food possible. Ms. Bridget Cromwell will still arrange your visit, help you through the day, and compensate you for your time at the end of the study using our ATM cards.



### CONTENTS

HANDLS Wave 3 Protocol Overview.....	1
HANDLS Wave 3.....	2
HANDLS New Arrival.....	2
HANDLS Kidney Function Study.....	6
Change of Address.....	7

### HANDLS NEW ARRIVAL

On Monday, June 8, 2009, Mobile Medical Research Vehicle 3 (MRV 3) was delivered to the National Institute on Aging's Intramural Research Program. Weighing in at 26,300 pounds and measuring 36 feet, MRV 3 was designed by LifeLine Technologies in Cincinnati Ohio. Keith Staton, our Logistics Manager, worked with Lifeline Technologies staff to



MRV 3 driver side

design a new vehicle. Based on your comments during and after your first visits, their primary mission was to provide more space for your comfort and privacy. The vehicle has office space, a rest room, an open space with 2 blood draw stations, and counter space to collect and process other samples. When we have finished collecting blood samples the office space will be used as an interview room and a place to do questionnaires.



MRV 3 participant entrance side

### HANDLS WAVE 3

The purpose of this study is to learn about changes in health over time. We want to study as many people in different communities as we can by using our Mobile Medical Research Vehicles (MRVs).

Our goal is to study the rate of health change, as people grow older. We plan to do this by studying the same people over many years. This gives us the information we want about how people's bodies change over time. We will continue to invite you to participate in our study every three to four years when we visit your neighborhood with our Mobile Research Vehicles (MRVs).

We also want to study why some people are healthier as they get older than others. We want to discover if we can predict the causes of good health with aging. If we can find the causes of good health, then we might find the cures for some of the diseases related to aging.

We are currently conducting the second visit to your neighborhood. The study data will be collected in two parts. The first part of the study consists of a visit to the MRVs. The MRV-1 will be used for the medical history and physical examination, body composition, test of the heart's function, strength testing and bone density. MRV-2 will be used for the dietary recall interview, questionnaires, and to administer the cognitive and memory testing. MRV-3 will be used for consenting, initial medical screening and the collection of laboratory samples. You will begin your visit on MRV-2 for consenting, screening and blood work. You will then proceed to either MRV-3 or MRV-1 depending on the schedule for the day. You will visit all three vehicles before the day is complete.

The second phase of the study will be conducted as a telephone interview and includes 2 questionnaires. First, you will be asked to complete another dietary recall interview including the use of dietary supplements. Then we will ask you complete another questionnaire that asks about your use of health care services, present health status, your level of physical activity, your neighborhood, mental health, household composition, if you provide care to others, and

any income and/or employment changes since your last visit to the MRVs.

### **List of Tests and Statements of Risk**

You may participate in some or all of our tests. You may stop any test anytime you want even after you agree to do it.

We want you to understand the risks in taking some of these tests. We welcome your questions about the tests and any risks even after the test starts.

Risks, if any, are stated and discussed with the description of the test, or in the section on Assessment of Risks in this booklet.

### ***Body Composition***

We will weigh you and measure various parts of your body. There are no risks from this test.

### ***Bone Density***

We will measure the size and quality of the bones in your back and hip. We will also perform the instant vertebral assessment (IVA), which allows for screening of vertebral fractures. These measures will tell us if you are likely to have osteoporosis (thinning of the bones) – a risk factor for bone fractures. We will also measure how much lean tissue and fat tissue you have in your body.

We will ask you to lie down on a device called a DEXA scanner. The scanner uses small amounts of X-ray radiation to make measurements as a detector examines your body. The risk to you, if any, is estimated to be slight. The risks are discussed in the section on Assessment of Risks in this booklet.

### ***Muscle Strength Testing***

*Grip Strength Test.* Handgrip strength in both hands will be measured using an adjustable, hand-held, hydraulic grip strength dynamometer. The hydraulic grip strength dynamometer is a device you hold in your hand and squeeze. It measures the strength of your handgrip.

You will be asked to sit with the arm to be tested resting on the table. The dynamometer is held in the

hand to be tested and is resting on a mouse pad. We will ask you to grip the two bars of the dynamometer in your hand, and to slowly squeeze the bars as hard as you can. The test is repeated on the other hand.

*Exclusions.* If you have had arm or hand surgery like fusion, arthroplasty, tendon repair, synovectomy, or other related surgery in the past 3 months you will not be tested on the affected hand.

*Chair Stand.* Using a standard armless chair placed securely against a wall, you be asked to rise from the chair without using your arms and to return to a seated position. If this is done successfully, you will be asked to repeat that movement 10 times.

*Exclusions.* There are no formal exclusions from attempting the single chair stand; inability to rise from a chair without using arms excludes participants from doing repeated chair stands.

### ***Balance Test***

We will ask you to stand with your feet together and with your feet in a heel-to-toe position for 30 seconds each. We will also ask you to try to stand on one leg for 30 seconds. You may stand on whichever leg is more comfortable. The examiner will demonstrate exactly what is expected. We will ask you to try to hold your foot up for thirty seconds. We will ask you to repeat this test 2 times.

The information we collect will help us to understand how strength changes as people get older.

We want you to know that there are very minimal risks associated with these tests. The only risks are that there is a slight risk of falling and you may feel tired after these tests.

### ***Medical History and Physical Examination***

*Medical History.* We will ask you questions about changes and updates to your medical history since your first MRV visit. The examiner will add information to the form when you have your physical examination.

*Smoking, Drug and Alcohol History.* We will ask you about your smoking habits and use of drugs and alcohol.

### ***Physical Examination***

Our physician or nurse practitioner will give you a physical exam in our private exam room. They will check your blood pressure and pulse in both arms. They will listen to your heart and lungs, examine your eyes, joints, and check your reflexes and other parts of your nervous system. The physician or nurse practitioner will also examine your abdomen.

Our physician or nurse practitioner will not do a complete physical exam. You should still see your personal physician for regular check-ups.

### ***Tests of your Heart Functions***

We will do a test to see how well your heart functions. We will discuss the results with you after we finish the tests. If we find a heart problem, we will discuss the problem with you and we will send the results to your personal doctor if you want us to.

*Echocardiogram.* An Echocardiogram is an ultrasound test that is used to examine the structure and function of the heart. We will measure the size of the chambers of the heart, the thickness of the walls, and the function of the chambers as the heart pumps. We will also examine how well the heart valves work as they open and close.

An ultrasound sensor is placed on the chest, over the heart. The echo sound waves produce images on the monitor. These images show the action of the chambers and valves of heart.

The only possible risk from this procedure is irritation from the electrodes placed on the skin.

### ***Nutritional Dietary Recall***

During this interview we will ask you to remember all the foods and beverages you have consumed during the last 24 hours. We will have some cups and measures to help you remember the amounts.

A trained interviewer will record your answers and ask questions designed to help you remember using a method developed by the United States Department of Agriculture (USDA).

The risks for the dietary recall interview are very minimal. The only risk of this part of the study is that you may become tired. All examiners who are involved in asking these questions are experienced in using these procedures and they will minimize any discomfort that you might feel.

### ***Problem Solving and Memory Testing***

We will ask you to do some tasks that exercise your thinking and memory. These tasks ask you to remember words, numbers, and pictures. These tasks also ask you to find similar words or to think of words beginning with certain letters or belonging to certain categories. They will also ask you to imagine how objects look in different positions.

The tests for remembering are called the Benton Visual Retention Test, the California Verbal Learning Test, and the Digit Span Test. The tests for words are called the Wide Range Achievement Test and the Category Fluency Test. The test for comparing objects is called the Identical Pictures Test. The test for switching letters and numbers is called the Trailmaking Test. The test for imagining objects in different positions is called the Card Rotations Test. Other tests, called Mental Status Tests, measure several types of memory abilities.

These tests are given in a private, quiet room with a tester who will help you understand how to do the best you can.

We want you to know that some people find these tests tiring. Sometimes, people feel nervous when they do these tests. All examiners who are involved in giving these tests are experienced in using these procedures and they will minimize any discomfort that you might feel. If the tests are disturbing you, then you may stop testing any time you want.

### ***Questionnaires***

We will ask you to complete several questionnaires about your use of health care services, present health status, your level of physical activity, your neighborhood, income and other financial interests, mental health, household composition, if you provide care to others, education and employment.

These questionnaires will be filled out on the Mobile Research Vehicles by using a computer and head-phones and during the telephone interview as part of phase 2. While on the MRV, we will help you do the questionnaires if you want us to. If you have trouble seeing or reading the questions you may ask one of our testers to help you. These tests are given in a private, quiet room.

### ***Blood, Tissue, and Urine Sampling***

If you agree, we will ask you to give us a blood sample and a urine sample. To prepare you for the blood tests we will ask you not to eat or drink anything after midnight the night before your visit to the MRVs. The blood draw will be performed right before you are served breakfast. We will use these samples to measure your health and so that we can measure changes in your health if we test you again. We will measure your white and red blood cells, your cholesterol, salt, and sugar, and how well your blood carries oxygen through your body and how fast you heal from minor cuts. We will also measure blood chemistry that may tell us how well your body organs work, such as the heart, liver, and kidneys. Women between the ages of 30 and 55 years will get a pregnancy test. We will be testing for communicable diseases including Hepatitis B, Hepatitis C, and Syphilis. You will be offered a test for HIV. If you decide to have the test, you will be asked to sign a separate consent form that explains the HIV testing procedures for the HANDLS study.

### ***Buccal Cell Collection***

As part of the medical evaluation buccal mucosa cells will be collected from you, if you agree, using the DNA Genotek Oragene RNA and DNA self collection system. This system collects buccal cells from inside your mouth by asking you to give a saliva sample by spitting into a small cup. The extracted DNA will be used for epigenetic analysis.

Doctors often make new discoveries by testing blood and urine. We would like to freeze a portion of your blood and urine samples to save them in our frozen tissue bank. We are not sure what new discoveries

will appear in the future. We want to set aside your samples until there are new tests that will help us understand health and aging.

More and more, we are discovering that our genes are important for understanding our health. Your genes are the parts of each cell inherited from your mother and father. Your genes are what make you a unique individual. Genes are made from DNA. We want to use some of your donated blood to freeze your DNA. We are not sure what studies will use your DNA. New studies may look at how your genes affect age-related diseases.

The samples saved in our bank will be stored at very low temperatures. Unlike household freezers, these freezers can preserve samples for many years, perhaps many decades. We will label your samples with code numbers. Only the principal investigators in this study will know your code number. Only researchers in this study will know the results of tests using your genes. We will not reveal your results to anyone who is not associated with this research.

We will ask you if you want the results of the tests that we perform on your blood and urine. We will also ask you if you want us to send your results to your personal physician. We do not plan to report the results of the studies we do on your genes because at this time, these tests do not diagnose or predict the development of specific diseases. In the future, we may offer you some of the results if the Food and Drug Administration approve some of the tests.

We will ask you to donate about 62 milliliters of blood (about 4 1/2 tablespoons). For comparison, the Red Cross usually asks for a donation of about 500 milliliters of blood (about two cups).

### **Compensation**

You will be paid up to \$220 (\$160 for the MRV visit and \$60.00 for the telephone interview) for participating in this study. You will receive a portion of the payment at the end of each phase. You will receive your payment in the form of an ATM debit card at the end of the each phase. If you do not perform all of the tests you will receive a portion of the payment. The ATM card will be activated before you leave the vehicle. You will be able to take the card to an ATM

machine in your neighborhood to withdraw your payment. We will provide round-trip transportation from your home to our mobile testing center if you want it. We will serve a box breakfast and box lunch if you are participating in tests during mid-day. We will do our best to meet your dietary needs if you have any.

You are participating in a research study and our physicians and technicians are not your primary health-care providers. We will provide medical feedback to you and, with your permission, to your personal physician about your health based on the tests in which you participate. If you need a referral to a physician, we will provide a list of local physicians.

### **HANDLS KIDNEY FUNCTION STUDY**

The purpose of this study is to use the most effective way to accurately measure renal function and identify early kidney disease in racially and ethnically diverse populations. We will directly measure your kidney function or GFR using blood clearance of a drug called Iohexol. Iohexol is a drug that contains iodine that is used in some types of X-rays. In fact you may have already taken this drug also caused a contrast material when you have had certain types of x-rays. It may also be used as a marker of how your kidney filters your blood. This will help us find out the best way to estimate kidney function in people from different racial and ethnic backgrounds. We will study kidney function as well as results from the other tests that are part of HANDLS. We will also try to find out if certain genes give people a higher risk of getting kidney disease. We will also store samples of blood and urine in case other tests become available in the future that will help to diagnose kidney disease.

For the study you will visit the ASTRA Clinical Unit at Harbor Hospital. We call this part of the Healthy Aging in Neighborhoods of Diversity across the Life Span study: Kidney Function in Diverse Populations (HANDLS-KFDP).

### **List of Tests**

*Blood, Tissue, and Urine Sampling.* If you agree, we will ask you to give us a blood sample and a urine sample. We will use these samples to measure your kidney function so that we can measure changes in your health if we test you again. We will measure blood chemistry that may tell us how well your kidneys work. Women between the ages of 30 and 55 years will get a pregnancy test. Doctors often make new discoveries by testing blood and urine. We would like to freeze a portion of your blood and urine samples to save them in our frozen tissue bank. We are not sure what new discoveries will appear in the future. We want to set aside your samples until there are new tests that will help us understand kidney health and aging.

More and more, we are discovering that our genes are important for understanding our health. Your genes are the parts of each cell inherited from your mother and father. Your genes are what make you a unique individual. Genes are made from DNA. We want to use some of your donated blood to freeze your DNA. We are not sure what studies will use your DNA. New studies may look at how your genes affect age-related kidney disease.

Tissue samples saved in our bank will be stored at very low temperatures. Unlike household freezers, these freezers can preserve samples for many years, perhaps many decades. We will label your samples with code numbers. Only researchers in this study will know your code number. Only researchers in this study will know the results of tests using your genes. We will not reveal your results to anyone who is not associated with this research.

We will ask you if you want the results of the tests that we perform on your blood and urine. We will also ask you if you want us to send your results to your personal physician. We do not plan to report the results of the studies we do on your genes because we have not learned enough to safely do so. In the future, we may offer you some of the results if the Food and Drug Administration approve some of the tests.

We will ask you to donate about 45 milliliters of blood. For comparison, the Red Cross usually asks

for a donation of about 500 millimeters of blood. Forty-five milliliters is equal to 3 tablespoons.

*The kidney function test.* For those who agree to participate, we will provide a detailed set of instructions. You will be asked to have a light meal the evening before and a light breakfast at home before you come for the visit. We will review all of your medications with you over the telephone one week before your visit. Some medicines can affect the test of we may ask you to stop taking some of those medicines before coming for your test. Everyone will be asked to drink two to three glasses of non-alcoholic, non-caffeinated beverages prior to coming for the study visit.

*Study day.* An intravenous line will be inserted at two different sites. A blood sample will be taken and then 5 ml of the study medicine, *Omnipaque 300 iohexol*, will be injected into one of the intravenous lines over a 60 seconds. After the medicine is injected, the intravenous line will be removed. Blood samples to measure the amount of drug that is still in your blood stream will be taken at approximately 10, 30, 120, 240, and 300 minutes from the second intravenous line. You are free to move around during the test. After the final blood sample, the second intravenous line will be removed; we will observe you for about 30 minutes and then we will send you home.

**Compensation**

As a volunteer, you will receive a monetary honorarium for participating in this study. If you participate in this part of HANDLS you will receive a total of \$100. We will provide round-trip transportation from your home to the National Institute of Aging ASTRA Clinical Research Unit at Harbor Hospital if you want it. We will serve a low protein lunch if you are participating in tests during mid-day. We will do our best to meet your dietary needs if you have any.

You are participating in a research study and our physicians and technicians are not your primary health-care providers. We will provide medical feedback to you and, with your permission, to your personal physician about your health based on the tests in which you participate. If you need a referral to a physician, we will provide a list of local physicians.

**CHANGE OF ADDRESS**

*Have you moved? Are you planning to move?*

It is important to us that we know exactly how to contact our participants. HANDLS is a longitudinal study. We will examine the same participants approximately every 3 years over the next 20 years.

We would like you to let us know if you have moved or if you are planning on moving soon. You may call us toll-free at 1-866-207-8363 (option 7) and we will take your change of address information over the phone.

If you prefer, you may complete the change of address form and mail it to us at:

HANDLS Study Change of Address  
National Institute on Aging  
5600 Nathan Shock Drive - Mailbox 6  
Baltimore, MD 21224

Our continuing contact with you is the key to the HANDLS study. Thank you so much for taking time to let us know how to stay in touch with you.

HANDLS Change of Address

Name \_\_\_\_\_

Old address \_\_\_\_\_

New address \_\_\_\_\_

Old area code & phone number \_\_\_\_\_

New area code & phone number \_\_\_\_\_

MRV location at last visit \_\_\_\_\_

# The Quarterly Newsletter for the HANDLS Community Healthy Aging in Neighborhoods of Diversity across the Life Span

The purpose of this study is to learn about changes in health over time. Using our medical research vehicles, we want to study as many people with different backgrounds as we can. We want this study to help us understand healthy aging by examining the effects of different backgrounds on changes in health over time. The information that we gather will help improve health and prevent disabilities. We want to do this for people from all backgrounds, particularly those in poor and minority communities.

For information about our study call 1-866-207-8363  
or visit our website [handls.nih.gov](http://handls.nih.gov)



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